

**REMARKS**

**Clarification of Continuation Status**

The Examiner has requested Applicant to provide a clear statement on the record as to which of the two applications, U.S. Patent Application Nos. 09/640,362 and 09/640,363, the instant application claims priority, because of an inadvertent discrepancy between previous responses by Applicant. Applicant hereby states for the record that the instant application claims priority to U.S. Patent Application **09/640,362**, as indicated in the amendment to the Specification introduced in the latest Response filed by Applicant on February 21, 2008.

**Rejections Under Judicially Created Doctrine of Obviousness-Type Double-Patenting**

The Examiner has rejected claims 2-3, 5-6, and 11 under the judicially created doctrine of obviousness-type double-patenting, contending that those claims are obvious and unpatentable variants of claims 1-4 of commonly owned U.S. Patent No. 6,426,342 (“the ‘342 patent”) in view of U.S. Patent No. 5,889,007 (“Pfister”). Regarding the claims of the ‘342 patent, the Examiner states:

The patented claims clearly provide for a method of treating a patient suffering from or susceptible to a condition known to result in loss of neuronal cells or less [sic] of neuronal cell function by reducing neuronal cell lose [sic] or function resulting from such conditions comprising the step of administration to said patient a neuroprotective amount of a bacterial beta-lactamase inhibitor (patented claim 1), such as clavulanic acid (patented claim 3).

The Examiner further states:

The patented claims further provide for a method for preventing neuron damage or the progression of neuronal damage in a patient suffering from or susceptible to disease states causing such neuronal damage comprising the step of administering to the patient a neuroprotective amount of a bacterial beta-lactamase inhibitor (patented claim 2), such as clavulanic acid (patented claim 4).

The Examiner admits that the patented claims do not recite the treatment of dementia as the condition known to result in loss of neuronal cell function or the disease state that causes neuronal damage. Nonetheless, the Examiner states that “the disclosure of the patent application is being relied upon solely to define the meaning of the term ‘condition known to result in loss of neuronal cells or neuronal cell function’ or ‘disease state that causes neuronal damage,’” which, according to the Examiner, is consistent with the MPEP at §804. In

support thereof, the Examiner refers to the MPEP, which states, “The specification can be used as a dictionary to learn the meaning of a term used in the patent claim.”

Applicant respectfully disagrees with the Examiner, and believes that the Examiner has improperly applied the MPEP guidelines to the claimed invention in view of the ‘342 patent claims. Thus, Applicant believes that the rejection of the instant claims is improper. The MPEP states:

A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim.

(§ 804.II.B.1). Applicant points out to the Examiner that in determining whether an obviousness-type double-patenting rejection is appropriate, the patented claims and instant claims must be read in isolation, claim for claim (MPEP § 804.II.B.1). The MPEP states that such a rejection is premised on looking at claims only (“When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art.”). However, the Examiner correctly indicates that the specification may be consulted for the definition of a claim term. Nevertheless, Applicant respectfully asserts that the Examiner has exceeded the boundaries of a proper consultation of the specification by improperly equating a species with the term allegedly needing a definition in an attempt to bootstrap the standing obviousness-type double patenting rejection.

The ‘342 patent claims a method of treating “a condition known to result in loss of neuronal cells or loss of neuronal cell function by reducing neuronal cell loss or function” by administration of a neuroprotective compound. In contrast to the ‘342 patent claims, the instant claims recite a method for treating “cognitive disorders in human patients in need of said treatment” by administration of a compounds “effective to modulate neurogenic carboxypeptidase or transpeptidase activity in the brain.” On their face, there is nothing about a disease known to result in a loss of neuronal cells or function that suggests a cognitive disorder. Moreover, there is nothing about a disease known to result in a loss of neuronal cells or function that suggests a disease that is responsive to modulating neurogenic carboxypeptidase or transpeptidase activity in the brain. Stated another way, Applicant’s claims to a method for treating “cognitive disorders in human patients in need of said treatment” by administration of certain compounds in amounts “effective to modulate

neurogenic carboxypeptidase or transpeptidase activity in the brain” cannot be fairly considered as obvious variants of the ‘342 patent claims to a method of treating “a condition known to result in loss of neuronal cells or loss of neuronal cell function by reducing neuronal cell loss or function.”

Thus, Applicant argues that the claims of the ‘342 patent and those in the instant application are not obvious variants of each, a conclusion that requires no additional information, least of all a definition. Moreover, Applicant asserts that the term recited in the ‘342 patent claims is in fact self-defining. In contrast, the Examiner suggests that a definition of disorders surrounding neuronal cells or neuronal cell function is needed. Even assuming arguendo that the term needs further clarification, which Applicant reiterates it does not, the Examiner’s proffered definition is in fact not a definition at all. Instead, what the Examiner has done is seek to equate such conditions with the single disorder dementia. The Examiner seeks to define the term “a condition known to result in loss of neuronal cells or loss of neuronal cell function by reducing neuronal cell loss or function” recited in the ‘342 patent by relying upon the ‘342 specification’s recitation of illustrative conditions, namely “seizure activity, such as that associated with epilepsy, ALS, Alzheimer’s disease, Huntington’s disease, Parkinsonism, and various forms of dementia such as multi-infarct dementia, vascular dementia, and neurodegenerative dementia” (‘342 patent, at col. 3. ll. 36-41). Even equating the terms in the ‘342 patent claims to the entire illustrative list would be improper, as that list is clearly presented as being non-exhaustive.

Consequently, the Examiner has attempted to equate cognitive disorders and neuronal cell disorders together by using dementia as some sort of a lynchpin. True, dementia is an example of a disorder that may “result in or from loss of neuronal cells or loss of neuronal function” (‘342 patent, at col. 3. ll. 36-36). However, an example that falls within the scope of a claim term is simply not a definition of that claim term. For example, “red,” though a “color” is not the definition of color. Therefore, though the use of the specification as a dictionary to discern the meaning of a term in the patent claim is allowed, Applicant respectfully asserts that the Examiner has improperly used an example of the disorder in the specification to draw out a definition that singles out dementia. Such a piecemeal approach does not comport with the requirement that the claims be read as a whole (*see, e.g.*, MPEP § 804.II.B.1, “[T]he analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness

determination. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).”..

Applicant respectfully suggests that the Examiner has confused an election of species as a basis for the piecewise rejection made herein. An election of species is to be used as a mechanism for examination of a broad claim. Applicant reminds the Examiner that Applicant’s prior election of dementia does not change the scope of the pending claims, but merely provides a convenient procedure for the Examiner to be used in searching the prior art. Thus, the election of species is only relevant in the context of 35 U.S.C. §§ 102 and 103, and not in the context of obviousness-type double patenting. While the Examiner’s search may reveal a reference which is useful in the context of an obviousness double-patenting rejection, to be consistent with the law, once identified, the claims of that reference must be read as a whole and compared to the pending claims as a whole to sustain a rejection that they are obvious variants of each other. Further reference to the species is inapposite.

Finally, with regard to the ‘342 patent, the Examiner also relies upon Pfister, presumably with specific reference to claims 5-6, which recite P-glycoprotein efflux pump inhibitors. Nonetheless, because Pfister is completely silent to the cognitive disorders recited in Applicant’s claims 2-3, 5-6, and 11, that reference does nothing to overcome the improper nature of the Examiner’s rejection. Accordingly, Applicant contends that the Examiner’s improper use of the specification does not support the obviousness-type double patenting rejection of claims 2-3, 5-6, and 11 over the ‘342 patent, either alone or in combination with Pfister. Applicant respectfully requests reconsideration of the standing rejection leading to its withdrawal.

The Examiner has also rejected claims 2-3, 5-6, and 11 under the judicially created doctrine of obviousness-type double-patenting over claims 1-2 and 5-6 of commonly owned U.S. Patent No. 6,610,681 (Koppel; the ‘681 patent) in view of Pfister, and of claims 1, 3, 6-7, 9-10, 14-15, 18, 27-28, 30 and 33-38 of commonly owned U.S. Patent No. 6,627,625 (Koppel; the ‘625 patent) in view of Pfister.

Applicant respectfully disagrees. Similar to the Examiner’s rejection discussed above, Applicant avers that the Examiner has again improperly delved into the specification of the relied-upon reference premised on finding a definition of “beta lactam compound” or “beta lactamase inhibitor.” Again, Applicant contends that those terms do not require any definition. The person of ordinary skill in the art knows, as should the Examiner, what is a beta lactam compound and a beta lactamase inhibitor. Regardless, the Examiner’s

attempt at defining those terms has instead resulted in equating them to Applicant's claim term clavulanic acid. Accordingly, Applicant respectfully contends that the Examiner has improperly consulted the specification in an attempt to bootstrap a rejection. Simply stated, Applicant believes that it is improper for the Examiner to use an example species as a surrogate for the generic claim term.

As stated above, in order for an obviousness-type double patenting rejection to stand, the claims must be obvious variants of each other. Applicant can only conclude that the Examiner has mistakenly confused dominance with obviousness. Applicant respectfully reminds the Examiner that such a rejection alleging that the instant claims are somehow dominated by the claims of either of the '681 patent or the '625 patent, because clavulanic acid is a species of the genus of either beta lactam compounds of beta lactamase inhibitors, is an improper basis and cannot support a rejection for nonstatutory double patenting.

Applicants refer the Examiner to MPEP § 804, stating, "Domination and double patenting should not be confused" ("Domination by itself ... cannot support a double patenting rejection," citing *In re Kaplan*, 789 F.2d 1574, 1577-78, 229 USPQ 678, 681 (Fed. Cir. 1986); and *In re Sarrett*, 327 F.2d 1005, 1014-15, 140 USPQ 474, 482 (CCPA 1964)).

Thus, parallel to the above arguments regarding the '342 patent, Applicant believes the Examiner has improperly consulted the specifications of the relied-upon references, and accordingly, the Examiner's basis for the rejection is unsupportable. In particular, the Examiner has attempted to equate the instant claim term "clavulanic acid" with the claim term "beta lactam compound" found in the '625 patent. Though clavulanic acid is certainly a beta lactam compound, the collection of all beta lactam compounds is not an obvious variant of the specific beta lactam compound clavulanic acid. The inverse is also true. It is well-settled law, that simple domination is not a proper basis without more for obviousness. The fact that clavulanic acid falls within the scope of the term "beta lactam compound" is insufficient standing alone to consider the two obvious variants of each other.

Nonetheless, in an effort to expedite prosecution, Applicant has amended claim 11 by deleting the term "behavioral disorder."

Finally, with regard to the '681 patent and the 625 patent, the Examiner also relies upon Pfister, presumably with specific reference to claims 5-6, which recite P-glycoprotein efflux pump inhibitors. Nonetheless, because Pfister is completely silent to the cognitive disorders recited in Applicant's claims 2-3, 5-6, and 11, that reference does nothing to overcome the improper nature of the Examiner's rejection. Accordingly, Applicant

contends that the Examiner's improper use of the specification does not support the obviousness-type double patenting rejection of claims 2-3, 5-6, and 11 over each of those references, either alone or in combination with Pfister. Applicant respectfully requests reconsideration of the standing rejection leading to its withdrawal.

**CONCLUSION**

Applicant believes that the foregoing remarks are fully responsive to the Examiner's Official Action mailed May 21, 2008, and that the claims of the instant application are now in condition for allowance leading to issuance. Such action is respectfully requested.

Respectfully submitted,  
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